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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/543,371	04/04/2000	Raghuram Kalluri	1440.1027005	6148

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EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/543,371	KALLURI, RAGHURAM	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/4/01 (received 1/4/02)* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/16/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Notice to Comply* .

RESPONSE TO APPLICANT'S AMENDMENT

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jessica Roark, Art Unit 1644, Technology Center 1600.

2. Applicant's amendment, filed 12/4/01 and received 1/4/02 (Paper No. 10), is acknowledged.
Claims 5-7 have been cancelled.
Claims 8-9 have been added.
Claims 1-4 have been amended.
Claims 1-4 and 8-9 are pending and are under consideration in the instant application.

3. Sequence compliance:
SEQ ID NO:10 of the sequence listing does not correspond to the sequence shown in Figure 18B and labeled as "SEQ ID NO:10". The sequence presented in the sequence listing as SEQ ID NO:10 is 244 amino acids in length and is a fragment corresponding to amino acids 2-245 of the Figure 18B sequence. In addition, the peptides of SEQ ID NO:10 found in the sequence listing refer to 245 amino acids, rather than 244. Reference to SEQ ID NO:10 is the specification appears to sometimes refer to the 244 amino acid sequence, and at other times refer to the 245 amino acid sequence.

The sequence presented in Figure 18B must also be represented in the sequence listing; therefore:

> *This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons set forth supra and on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.*

Applicant is reminded to amend the specification (including the Brief Description of Drawings), drawings and claims as appropriate to reflect compliance with the Sequence Rules.

Applicant is requested to carefully review the specification, drawings and sequence listing to determine the correct sequence reference and the corresponding numbering of the fragments.

Applicant is reminded that any changes to the specification must point to a basis in the specification as filed so as to not introduce New Matter.

4. The information disclosure statement filed 1/4/02 and received 1/14/02 fails to comply with 37 CFR 1.97(c) because it lacks both the fee set forth in 37 CFR 1.17(p) and the statement required under 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

5. This Office Action will be in response to applicant's arguments, filed 12/4/01 (Paper No. 10). The rejections of record can be found in the previous Office Action (Paper No. 8).

It is noted that New Grounds of Rejection are set forth herein.

6. Applicant's comments, filed 12/4/01, with respect to the requested change to the title to reference fragments of the α3 (IV) NC1 domain of Collagen (Tumstatin) are acknowledged.

However, MPEP 606.01 states that where the title is not descriptive *of the invention claimed*, the examiner should require the substitution of a new title *that is clearly indicative of the invention to which the claims are directed.*

Applicant should amend the title accordingly.

7. Applicant's comments, filed 12/4/01, with respect to the request to add to the abstract reference to fragments of the α3 (IV) NC1 domain of Collagen (Tumstatin) are acknowledged.

MPEP 608.01(b) sets forth the requirements of an abstract, and indicates that the content of a patent abstract should be such as to enable the reader thereof, regardless of his or her degree of familiarity with patent documents, to ascertain quickly the character of the subject matter covered by the technical disclosure *and should include that which is new in the art to which the invention pertains*. Thus while the abstract need not be limited to the claimed invention, the claimed invention should be included.

Applicant should amend the abstract accordingly.

8. Applicant's request for clarification with respect to the priority date of the claims, filed 12/4/01, is acknowledged.

First it is noted that SEQ ID NO:10 of parent USSN 09/335,224 and SEQ ID NO:10 of instant USSN 09/573,371 are not the same, as noted supra. SEQ ID NO:10 of '224 is 245 amino acid in length, while SEQ ID NO:10 of '371 is 244 amino acids in length and corresponds to amino acids 2-245 of SEQ ID NO:10 of '224.

Support has been assessed based upon the sequences as claimed, taking into account Table 2 of '371, Figure 18 of '371, and the sequence listing. A summary follows:

Peptide length	sequence 5' and 3' ends	Corresponding fragment for: '224 SEQ ID NO:10	'371 SEQ ID NO:10	Names	Described in '224	'371
245	PGLK...KKRH	1-245	(Fig 18B)	Tumstatin?	+	+
244	GLK....KKRH	2-245	1-244	Tumstatin?	+	+
191	QRAH....KKRH	55-245	54-244	Tum-1/"N-53"	+	+
124	GLK....RCTV	2-125	1-124	Tum-2/Tum333	+	+
120	CEGP...KKRH	126-245	125-244	Tum-3/Tum334	+	+
64	EFRA...KKRH	(182-245)	181-244	Tum-4	-	+
71	QRAH...RCTV	(55-245)	54-124	anti-angiogenic core	-	+
19	SPFL...SNSY	(186-204)	185-203	anti-tumor core	-	+
133	GLK...AIAI	(2-133)	(1-132)	not identified	-	-

Residues 54-124 and residues 185-203 of SEQ ID NO:10 ('371) are described on page 35 of the instant application ('371) as defining the regions of Tumstatin corresponding to anti-angiogenic and anti-tumor cell activity, respectively. A description of these species of the genus of Tumstatin fragments was not found in parent '224, nor was a fragment having amino acid residues 1 to 132 of SEQ ID NO:10. Provisional applications 60/089,689 and 60/126,175 also do not appear to provide adequate written support for these fragments.

The filing dates of claims reciting these particular fragments (i.e., claims 4, 8 and 9; but not claims 1-3) are therefore deemed to have the filing date of the instant application, filed 4/4/00, as no support was found for these fragments in priority documents 60/126,175, 60/089,689 or 09/335,224.

It is further noted that there does not appear to be adequate written support of *any particular fragment* of Tumstatin in provisional documents 60/126,175 or 60/089,689. The limitation of "an isolated non-Goodpasture fragment of the α3(IV)NC1 domain does not appear to have an adequate written description either, as no such fragments are discussed in the provisional applications. *Thus the priority date of claims 1-3 is considered to be 6/17/99, the filing date of parent USSN 09/335,224.*

Applicant has asserted in the response filed 12/4/01 that the instant claims are entitled to a priority date of June 17, 1998 because the description of various anti-angiogenic fragments in the priority documents provides adequate written support for the instant species of fragments of the α3(IV)NC1 domain which have the amino acid sequences of residues 54 to 124 of SEQ ID NO:10, residues 1-132 of SEQ ID NO:10 or residues 181 to 244 of SEQ ID NO:10.

Applicant's belief that the priority documents provide an adequate written support for the instant claims relies on the argument that since some anti-angiogenic fragments were disclosed in the priority documents, that description of a genus of fragments provides support for the instant individual species.

However, in Purdue Pharma L.P. v Faulding Inc., 56 USPQ2d 1481, 1486 (CA FC 2000) the Court noted with respect to In re Ruschig 379 F.2d 990, 154 USPQ 118 (CCPA 1967) that "Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say 'here is my invention.' In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure. See [In re Ruschig] at 994-95, 154 USPQ at 122; Fujikawa, 93 F.3d at 1570-71, 39 USPQ2d at 1905; Martin v. Mayer, 823 F.2d 500, 505, 3 USPQ2d 1333, 1337(Fed. Cir. 1987) ("It is `not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure. ... Rather, it is a question whether the application necessarily discloses that particular device.'") (quoting Jepson v. Coleman, 314 F.2d 533, 536, 136 USPQ 647, 649-50(CCPA 1963))".

In the instant case such blaze marks do not appear. Thus contrary to Applicant's assertions, the observation by the previous Examiner that the fragments could not be identified in the priority documents is sufficient to meet the initial burden of the Examiner.

Neither the previously recited fragments nor the instantly recited fragments are considered to be entitled to the filing date of any of the priority documents.

9. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP 608.01(o). Correction of the following is required:

Applicant is requested to identify the written support for claim 8, particularly the claimed limitation of an isolated fragment having the amino acid sequence of amino acid residue 1 to amino acid residue 132 of SEQ ID NO:10.

10. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Hyperlinks appear at least on page 47 at lines 21 and 23.

11. Applicant's cancellation of Claims 5-7 have obviated the previous objections and rejections with respect to Claims 5-7.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed. *This is a New Matter rejection for the following reasons*:

Applicant's amendment asserts that no New Matter has been added and points to the specification at pages 34-35 for support for the newly added limitation "amino acid residue 1 to amino acid residue 132 of SEQ ID NO:10". However, the specification does not appear to provide an adequate written description of an isolated fragment that has "amino acid residue 1 to amino acid residue 132 of SEQ ID NO:10". The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action.
Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

14. Claims 1-3 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments, filed 12/4/01, have been fully considered but have not been found convincing, essentially for the reasons of record in Paper No. 8.

The instant claims are now drawn to compositions comprising a first isolated non-Goodpasture fragment of α3(IV)NC1 domain having the ability to bind the $\alpha_v\beta_3$ integrin in an RGD-independent fashion and/or the ability to inhibit proliferation of endothelial cells wherein the fragment is unable to inhibit tumor cell proliferation.

Applicant argues that a structural basis is provided by the claims. The basis of these several arguments appears to rely on equating the α3(IV)NC1 domain with SEQ ID NO:10, then arguing that SEQ ID NO:10 does provide a structural basis.

However, the α3(IV)NC1 domain does not appear to be limited to SEQ ID NO:10, as argued by Applicant. Although page 32 at lines 8-11 discloses that fragments of SEQ ID NO:10 are fragments of the α3(IV)NC1 domain; the α3(IV)NC1 domain may comprise more than SEQ ID NO:10 (i.e. fragments of SEQ ID NO:10 are only a subset of fragments of the α3(IV)NC1 domain). Thus "an isolated non-Goodpasture fragment of α3(IV)NC1" does not appear to be a defined structure. In the absence of a defined structure from which the fragments are derived (e.g., SEQ ID NO:10), there does not appear to be a sufficient correlation of structure and function.

Applicant further argues that there are several disclosed species that provide a representative number of species sufficient to provide an adequate written description.

Although several species are disclosed, the essential structural feature of these species that provides the recited functions is not provided in the instant claims. In the absence of such a structural feature (e.g., a core sequence that defines a function) then one of ordinary skill in the art would not reasonable conclude that Applicant was in possession of the genus based upon disclosure of a few species.

Thus the present Examiner must also conclude that the disclosed fragments of SEQ ID NO:10 do not represent the *genus* of α3(IV)NC1 fragments with the instantly recited functions.

Consequently, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention. See *Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).* Applicant is also directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The rejection is therefore maintained, essentially for the reasons of record.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Applicant is reminded that for examination purposes, "having" is interpreted as open (i.e., "comprising") language.

17. Claims 1-4, 8 and 9 are rejected under 35 U.S.C. §102(b) as being anticipated by Kalluri et al. (J. Biol. Chem. 271(15):9062-9068, 1996, IDS #AW, see entire document).

Applicant's arguments, filed 12/4/01, have asserted that in view of the amendment of claims 1-3 to recite a composition and the presence of functional language in the claims, the rejection of record in Paper No. 8 does not apply.

As previously noted, Kalluri et al. teach an isolated non-Goodpasture fragment of α3(IV)NC1 which comprises (having) the fragments of amino acids 54-124 of SEQ ID NO:10 (see page 9066 and figure 4 in particular).

With respect to Applicant's assertion that the fragments of α3(IV)NC1 taught in Kalluri et al. do not have the instantly recited functional properties, these functions would be inherent properties of many of the fragments taught by Kalluri et al. For example, the α3/n-26/c-36 fragment is a non-Goodpasture fragment (Figure 4c in particular) that would inherently have the properties recited in instant claims 1-3.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

In addition, Kalluri et al. place the α3/n-26/c-36 and other fragments in a composition comprising a pharmaceutically-acceptable carrier by diluting fragments into diluted serum for the antibody inhibition assay described in Figure 5.

The teachings of Kalluri et al. also anticipate instant claim 4 because this independent claim only requires an isolated peptide comprising amino acids 54-124 of SEQ ID NO:10, and isolated fragments of α3(IV)NC1 described throughout Kalluri et al. meet this limitation.

In addition, Kalluri et al. teach an isolated fragment of α3(IV)NC1 which comprises (having) amino acids 1-132 of SEQ ID NO:10 (e.g., all of the α 3/c point mutation fragments would meet this limitation since each is a fragment of α3(IV)NC1 that comprises amino acids 1-132 of SEQ ID NO:10). Thus newly added independent claim 8 is anticipated.

Kalluri et al. also teach an isolated fragment of α3(IV)NC1 which comprises (having) amino acids 181 to 244 of SEQ ID NO:10 (e.g., the α 3/n-26 fragment would meet this limitation since it is a fragment of α3(IV)NC1 that comprises amino acids 181-244 of SEQ ID NO:10). Thus newly added independent claim 9 is also anticipated.

Applicant is reminded that "[W]hen, as by recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if *one* of them is in the prior art." Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing In re Petering, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original); and see the concurring opinion in Ex parte Lee, 31 USPQ2d 1105 (Bd. Pat. App. & Inter. 1993). See MPEP 2131.03. The "having" language of the instant claims reads on any fragment possessing the core sequence range recited.

Therefore, the reference teachings anticipate the claimed invention and the rejection is maintained.

17. Applicant's provision of related applications USSN 09/479,118 and USSN 09/625,191 and the pending claims for each is acknowledged.

In view of the subject matter of the pending claims of USSN 09/625,191; the following obvious-type double patenting rejection is set forth.

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-4 and 8-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/625,191. Although the conflicting claims are not identical, they are not patentably distinct from each other because the having/comprising language of the fragments reads on one another and the functional properties are shared. In addition, to formulate a fragment with the instantly recited functional properties as a composition in a pharmaceutically-acceptable carrier would have been obvious to one of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. No claim is allowed.

21. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
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March 11, 2002

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